Omnitest® plus

Blood Glucose Monitoring System

www.omnitest.bbraun.com

B|BRAUN
SHARING EXPERTISE

Important information

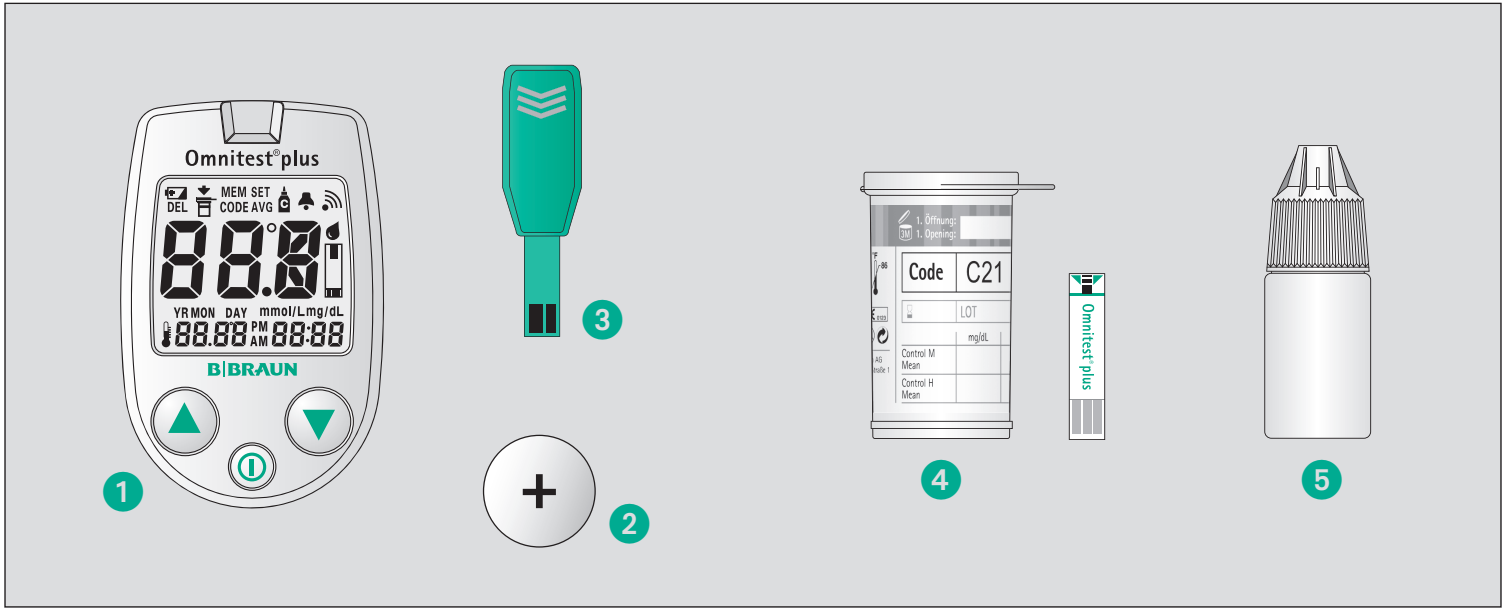
The **Omnitest® plus** system provides a quick and easy way to measure the blood glucose level. **Omnitest® plus** could be used for self-monitoring of blood glucose level by diabetes patients.

It should be used only for testing blood glucose (sugar) and only with fresh capillary whole blood samples. It should not be used for the diagnosis of diabetes or for the testing of newborns (neonates). Do not use **Omnitest® plus** system for any purpose other than blood glucose test. The **Omnitest® plus** system is intended for use outside the body (in vitro diagnostic use only).

Warning

Before using **Omnitest® plus** meter, read all instructions in this manual and the additional information given in instructions for use of the test strips. Practice for accurate and safe test. You should have commentary recommendation from your diabetes care professional for the proper use of this meter and daily management of your diabetes.
Do not change your therapy due to blood glucose results of the **Omnitest® plus** system without prior consulting your physician.

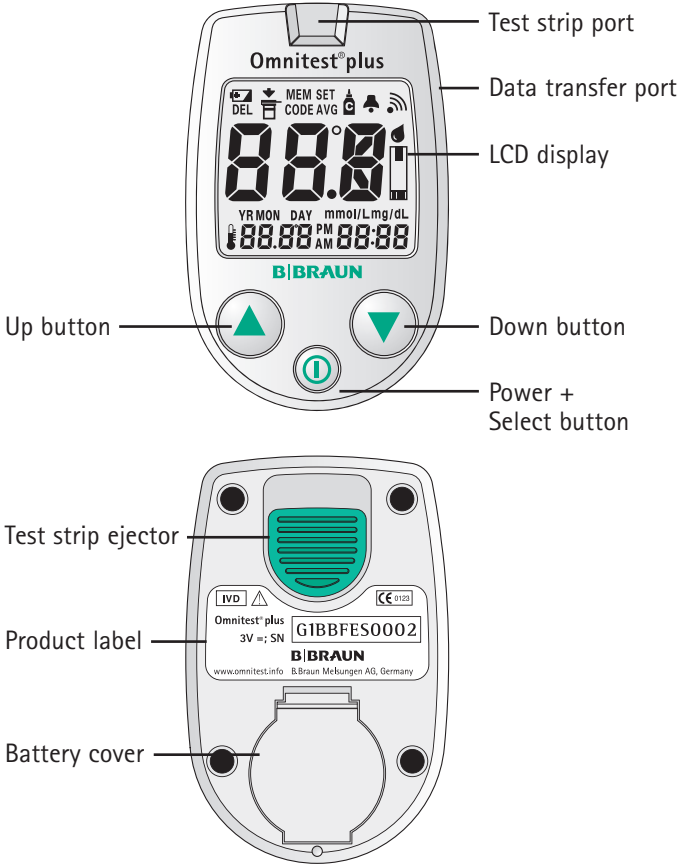
Content



1. **Omnitest® plus** meter
2. One 3V Li-battery (CR2032)
3. Check strip
4. **Omnitest® plus** test strips (may be sold separately)
5. **Omnitest® plus Control** control solution (sold separately)

Check your **Omnitest® plus** system to contain all parts shown at the outer packaging. If anything is missing, please return your system to the place of purchase or contact your nearest B. Braun representative.

The Meter

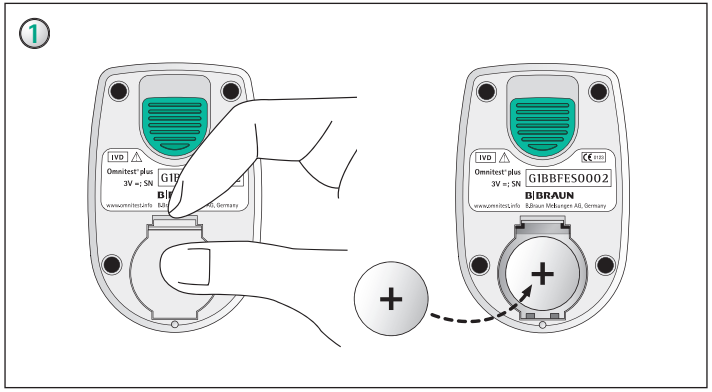


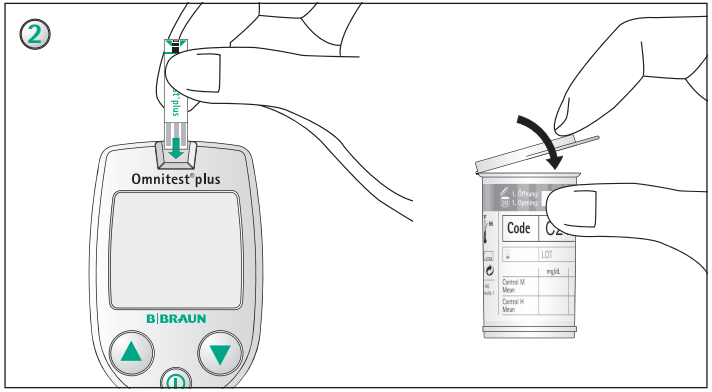
Display Segments

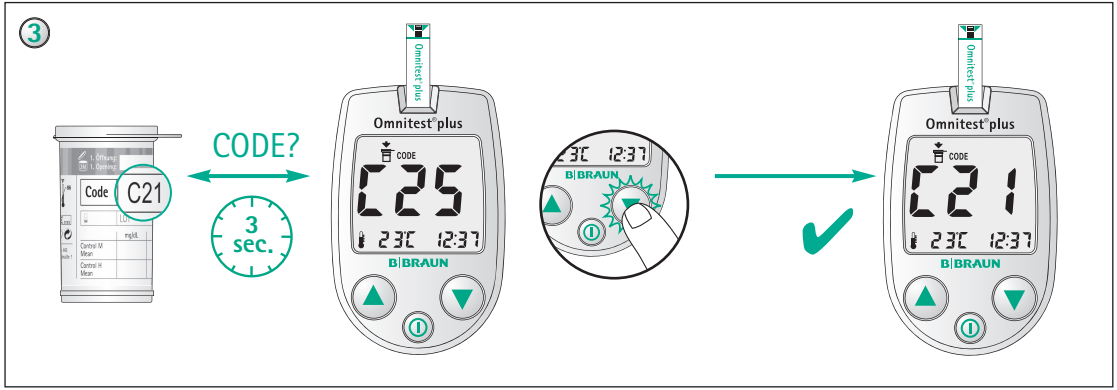
Segment	Meaning
	The battery symbol means the battery is low and should be changed soon.
DEL	The "DEL" mark will display when you can delete results from the meter memory.
	Close the test strip vial cap.
MEM	The "MEM" mark will display while reviewing the results.
SET	The "SET" mark will display during ALL meter setting.
CODE	The "CODE" mark will display while coding the meter.

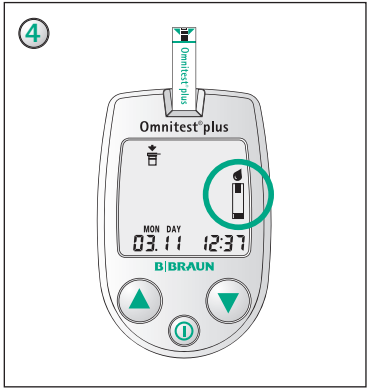
Segment	Meaning
AVG	"AVG" is displayed when average results are shown.
	Control solution symbol
	Alarm symbol
	Buzzer symbol
	Sample applying symbol
mmol/L mg/dL	Test result unit
	Temperature symbol
YR MON DAY	Year Month Day
AM PM	0 - 12 o'clock 12 - 24 o'clock

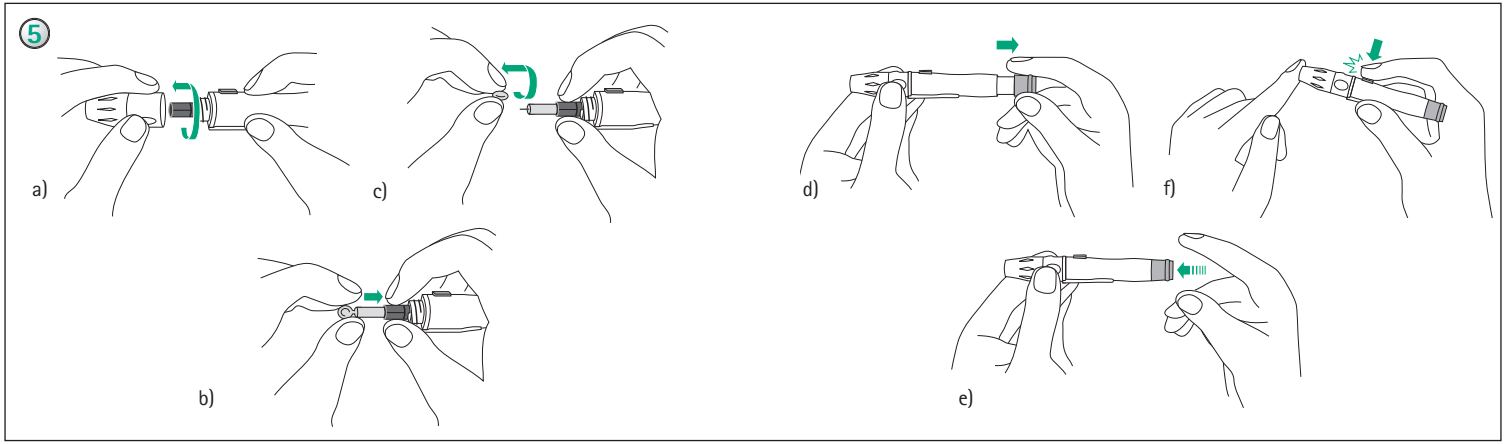
Quick Reference

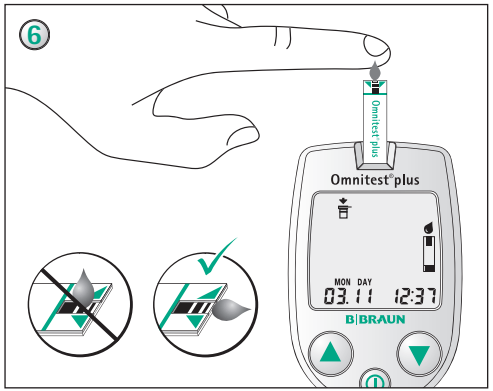


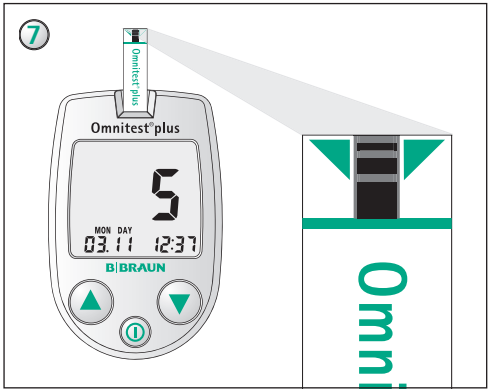


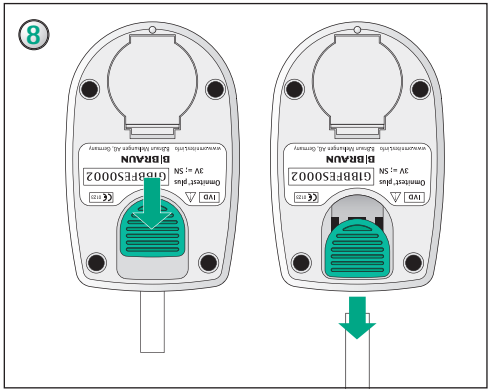





5
a)
c)
b)
d)
f)
e)

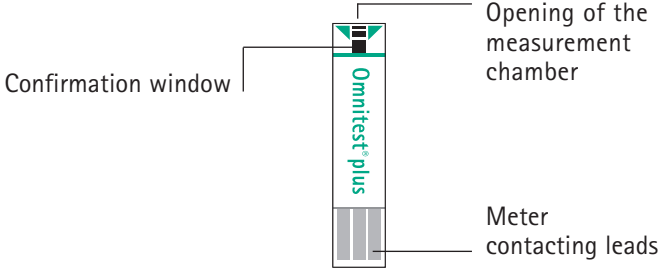

6
Omnitest plus
Omnitest®plus
MON DAY
03.11 12:37
B|BRAUN


7
Omnitest plus
Omnitest®plus
5
MON DAY
03.11 12:37
B|BRAUN
Omni


8
B|BRAUN
Omnitest plus
3V ⎓ SN
GIBBFES0002

Omnitest® plus Blood Glucose Test Strip

Omnitest® plus test strips are only to be used with **Omnitest® plus** meter for accurate analysis of your blood glucose level.
Use the test strip exactly as described in the user's manual for **Omnitest® plus** test strips.



Storage and Handling:

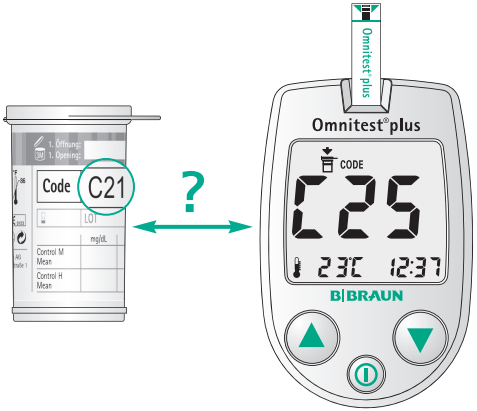
- Prior to first use. Check that the vial is undamaged and closed.
- Store the **Omnitest® plus** test strip vials in a cool, dry place between 2 - 30 °C (36 - 86 °F). Do not refrigerate or freeze. Keep out of direct sunlight. Do not use test strips which had been stored under inappropriate conditions.
- Store test strips in its original vials only. Do not put the test strips in new vials or in any other container.
- Close the vial cap tightly immediately after removing an **Omnitest® plus** test strip. This keeps the strips fully functional right up to the expiry date.
- Use test strip immediately after removing it from the vial.
- Do not use test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
- Make a notation of the date on the vial label when you first open it. Discard remaining **Omnitest® plus** test strips 3 months after first opening the vial.
- Avoid getting dirt, food or water on the test strip. Do not handle test strips with wet hands. All parts of the test strip could be touched with dry and clean fingers.
- Do not bend, cut, or alter an **Omnitest® plus** test strip.
- **Omnitest® plus** test strips are for single use only.
- Do not perform blood glucose tests at temperature below +10 °C (50 °F) or above +40 °C (104 °F), above 90 % relative humidity.
- **Warning!** Keep the test strip bottle away from children. A child could choke on the cap or the test strips. The test strip and the vial wall contains agents that may be harmful if swallowed.

Note

Please refer to the user's manual for **Omnitest® plus** blood glucose test strip for additional information.

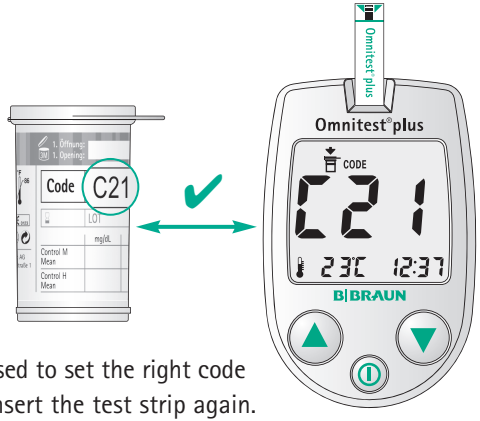
Code the Meter

Code numbers are used to calibrate the **Omnitest® plus** meter for accurate results. You must confirm the code number of the test strip vial with the number shown on the meter, before using **Omnitest® plus** test strips.



Insert **Omnitest® plus** test strip to turn on the meter. The code number will appear on the display for 3 seconds. Compare the code number (example; C25) on the meter's display with the code number on the test strip vial. If these two code numbers match, you can start testing. If these two code numbers do not match, you must code the meter according to the test strip vial code number.

Press ▲ button to increase the code number or ▼ button to decrease the code number. The number increases or decreases by one digit every time you press ▲ or ▼ button while the code number appears on the display. The code number increases or decreases automatically and fast while holding to press ▲ or ▼ button.



If you missed to set the right code number, insert the test strip again.

Caution

Without matching the code numbers, you will not get accurate test results of your blood glucose level.

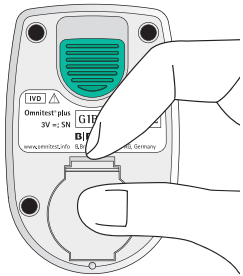
Battery

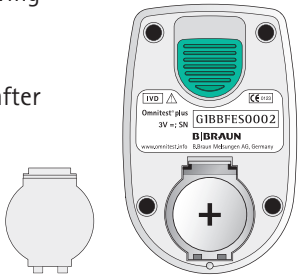
Change the battery when the battery icon appears on the display or when the meter does not power on by any means.

The meter needs only one 3V Li CR2032 battery. One battery is provided with the **Omnitest® plus** meter system. When changing battery, pay attention to the polarity, which is printed in the battery holder of the meter. The plus of the battery has to face up.

If the new battery is inserted, at first all segments of the display will be shown. Thereafter an internal check of the electronic takes place in the following seconds.

Correct the date and time setting after the battery change.

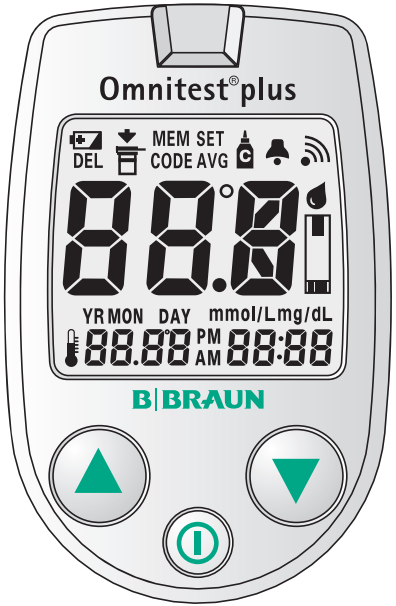




Checking the Meter Display

Each time you enter a new battery, all segments of the display will appear for 3 seconds. The numbers displayed later are only meant for internal tests of the electronics.

The following picture shows all possible display segments, so that you could check that the display is working properly.



Check Strip

The **check strip** is used to prove that the **Omnitest® plus** meter is working properly. Insert **check strip** into meter, facing "‹‹‹" up. Meter will be automatically turned on.

If an error message is displayed, repeat 2 or 3 times. If it is still not ok, do not use the meter for blood glucose monitoring. Please contact your local distributor for warranty services. It is recommended to do this test before first use and always if you suspect the meter is not properly working.

Using Control Solution

The **Omnitest® plus Control** solution is used to check that the blood glucose monitoring system consisting of the meter and the test strips is working correctly.

Use only **Omnitest® plus Control** solution for the **Omnitest® plus** monitoring system.

The control solution should be used

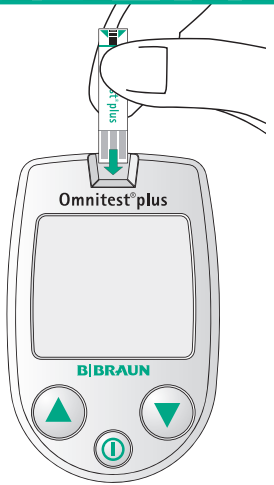
- Whenever you suspect the meter or test strip is not functioning properly.
- If your blood glucose test results are not consistent with your symptoms or if you think they are not accurate.
- If you have dropped the meter.
- For quality control in the point of care usage.
- For teaching or learning the system.

To perform a control solution test, follow the same test procedure as for a blood glucose test, substituting control solution for the drop of blood. For detail instruction, see page 35 "Testing Your Blood Glucose".

Using Control Solution

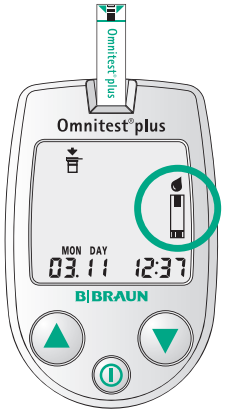
① Insert Test Strip

If the control solution is cold, do not use until the solution has warmed up to room temperature. Control solution tests have to be done in a temperature range 20 – 25 °C (68 - 77 °F). Insert a test strip. Push the test strip until it will go no further without bending the strip. The meter will turn on automatically. Match the code number to the code printed on the test strip vial.



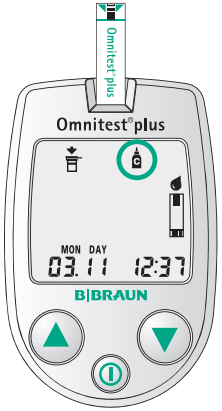
② Control Solution Test Mode

When blood and test strip symbol appears, press ▲ or ▼ button to mark the test as a control solution test in the meter memory.

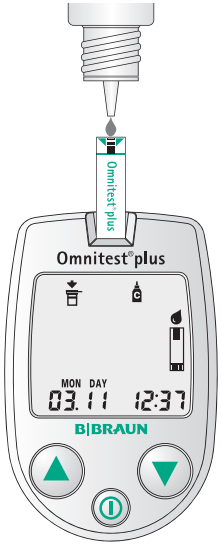


③

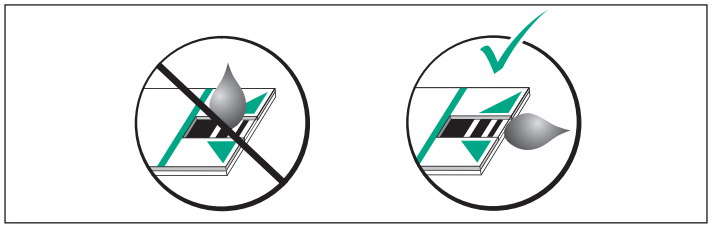
Control solution symbol C appears on the display. If you decide not to do a control solution test, press the ▲ or ▼ button again to remove control solution symbol from the display.



④ Apply Control Solution



Shake the control solution vial gently. Remove the cap. Squeeze the vial, discard the first drop, and wipe off the dispenser tip with a clean tissue to ensure an accurate result. Squeeze the vial again to get a drop. Apply the hanging drop to the tip of the test strip until the drop is drawn into the test strip. Once you hear the "beep", it means the test strip is completely filled. The meter begins to count down 5 to 1 and then the result is displayed. **Compare the result displayed with the range printed on the test strip vial. The result should fall within the range.**



Comparing Control Solution Results

If test results fall outside the range, repeat the test. Out-of-range results may be caused by one or more of the following causes:

- Error in performing the test.
- Failure to shake the control solution vial gently.
- Expired or contaminated control solution.
- Control solution that is too warm or too cold.
- Failure to discard the first drop of control solution and wipe the dispenser tip clean.
- Contamination of the control solution e.g. if the drop of the control solution is taken back into the control vial.
- Improper coding of the meter.
- Meter malfunction.
- Test strip deterioration.

Do not use the system to test your blood glucose until you get a control solution test result that falls within the range.

Note

Mark all control solution tests with C symbol to distinguish from blood glucose tests in the meter memory. Marked control solution test results will not be included in your averages.

Set the Meter

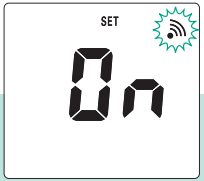
The **Omnitest® plus** meter has 7 functional setting modes

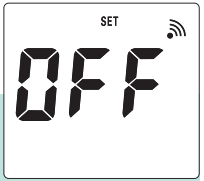
1	buzzer
2	12 hour/24 hour
3	date and time
4	test result unit (mg/dL or mmol/L)
5	temperature unit (°C or °F)
6	average day
7	alarm

If you need to change any of the above settings, you need to enter the setting mode. Turn on the meter by pressing ⓘ button and hold for 3 seconds. This will initiate the "Set the Meter" mode. SET icon will appear on the display during the setting.
To leave the "Set the Meter" mode at any time, press the ⓘ button for 3 seconds.
If you have missed out a setting, start the "Set the Meter" procedure again.

Set the Buzzer

Turn on the meter by pressing ⓘ button and hold for 3 seconds. Buzzer icon will appear on the display. Press ▲ or ▼ to select ON/OFF the buzzer sound.



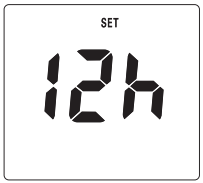


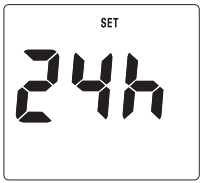
Note

There is no beep sound during buzzer is OFF when test strip is inserted and when test result pops up.

Set the 12 Hour or 24 Hour mode

After selecting ON or OFF press ⓘ for hour mode setting. Press ▲ or ▼ button to select the proper time system. And then press ⓘ button to set the date and time.

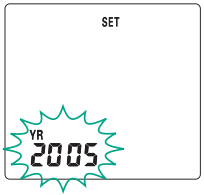




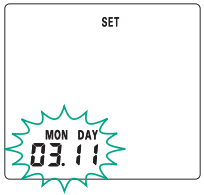
Set the Date and Time

Press ▲ or ▼ button to select the year. With the correct year on display, press the ⓘ button and the month setting will start flashing. Press ▲ or ▼ button to select the month and then press ⓘ button to set the day. After then press ⓘ button to set time. Press ▲ or ▼ button to select the appropriate hour, press ⓘ button to set minutes.

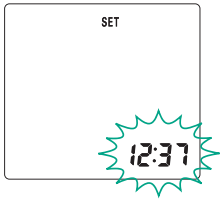
1) Year setting



2) Month and day setting



3) Time setting



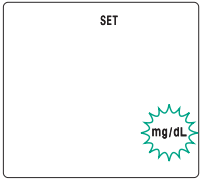
(The year can range from 2005 to 2099, which is not displayed in normal operation)

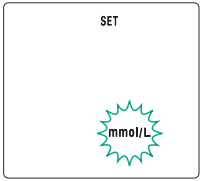
Note

Without setting the date properly, the average glucose level and the results in memory will not show proper value. It is highly recommended to set the meter before use and to check the time when a new battery is installed. You can not test your blood glucose while in the setting mode.

Set the Test Result Unit

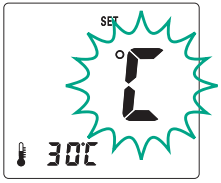
Press ⓘ button to set the test result unit. You should now be at the unit of measurement selection. Select the proper unit of test result (mg/dL or mmol/L) for your blood glucose measurement by pressing the ▲ or ▼ button.

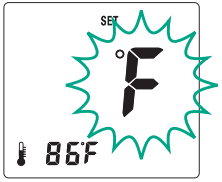




Set the Temperature Unit

Once the unit of test result is selected, press the ⓘ button to set the temperature unit. Press ▲ or ▼ button to select the proper temperature unit.

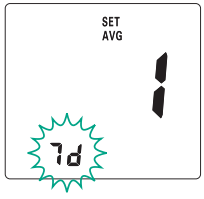




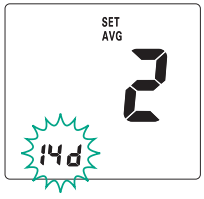
Set the Average Day

Press ⓘ button to proceed to set the Average Day. **Omnitest® plus** will show 3 different average results and the number of days can range from 1 to 99 days. The setting mode begins with setting the number of days of which you would like to receive an average calculation of your glucose level. To increase or decrease the number of days, press the ▲ button or ▼ button; holding the ▲ or ▼ button the value will be increased or decreased at a quick rate. With the correct number of days displayed, press ⓘ button to set next average day. AVG character will display during the average day setting.

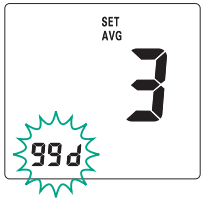
1) First average setting



2) Second average setting



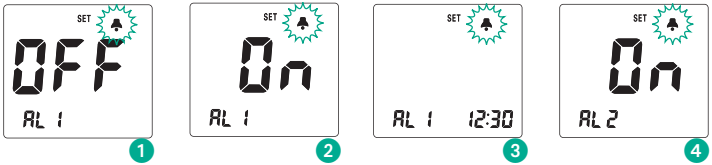
3) Third average setting



Set the Alarm

Omnitest® plus has 5 different alarm settings. The bell icon will be displayed during the alarm setting. Alarm setting order is AL1 ➠ AL2 ➠ AL3 ➠ AL4 ➠ AL5. If the AL2 is OFF the rest of AL3 ~ AL5 is all OFF.

1. Press ▲ or ▼ button to select the ON/OFF of alarm function.
2. If you choose ON, press ⓘ button to set the time for alarm.
3. Press ▲ or ▼ button to set the proper alarm time (hour), press ⓘ button to set minutes.
4. Press ⓘ button to set next alarm.



Note

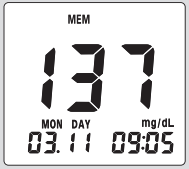
Press either ▲, ▼ or ⓘ button to stop the alarm. The alarm will not work during the testing of blood glucose. The loudness of the alarm is intended to remind you at a glucose measurement but not to wake you up from deep sleep.

Reviewing Your Results

Omnitest® plus saves up to 250 test results in built-in memory and 3 different average glucose levels are calculated and saved. These values will appear on the display by recalling anytime you like to see them. The latest result will replace the oldest beyond 250 data.

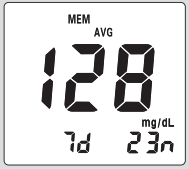
The meter enters "Memory" mode by pressing the ⓘ button shortly.

The first display shows the latest test result.



Press ▼ to see the individual test results.

Press ▲ button to see the average results. Small AVG icon will be shown on the display (7d = 7 days average; 23n = 23 results taken for average calculation).

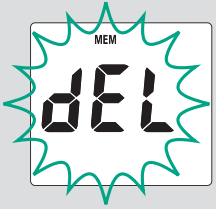


Deleting Test Results

To delete any individual test result in the memory press ▲ or ▼ button for 3 seconds.

Small DEL icon will be shown on the left-up of the display. Press ▲ or ▼ button until 2 beeping sounds will be heared and the test result disappears from the display.

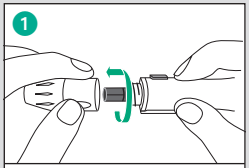
To delete all test results press ▲ ▼ buttons at the same time for 2 seconds and then big dEL character will be displayed. Keep on pressing ▲ ▼ buttons until 2 beeping sounds will be heared and dEL disappears from the display.

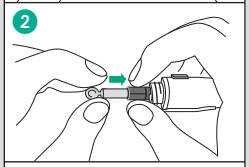


Average results (AVG) can not be deleted, because they are calculated from the remaining test results in the memory.

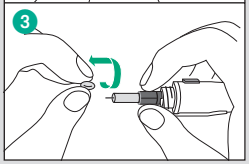
Collecting a Drop of Blood Sample

Unscrew the **Omnilance** tip and insert a new **Omnican**® lancet firmly into the carrier.





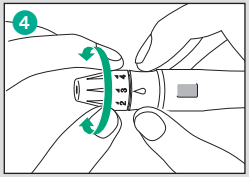
Next pinch the lancet and twist off the protective cover. Replace the threaded tip of the **Omnilance** device.



The comfort tip offers 5 different levels of skin penetration.

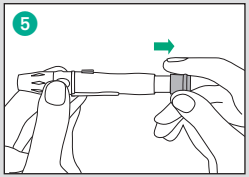
To select best depth:

1–2 for soft or thin skin
3 for average skin
4–5 for thick or calloused skin

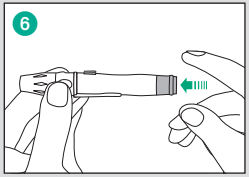


To select a desired depth, move the number to match the arrow.

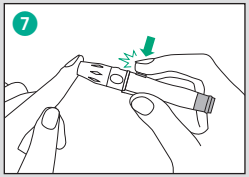
Next hold the tip in one hand and pull on the sliding barrel with the other hand. As the ends are pulled apart, the spring tension increases. When a click is felt, the spring tension is locked and the device is ready for use.



Release the sliding barrel. It will automatically move back to its original position near the trigger hub.



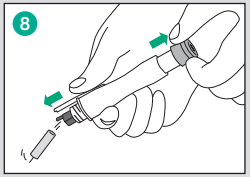
Place **Omnilance** against the tip of the finger. Next press the trigger and lift up the device.
It is less painful to prick you at the side of the finger tip.



Set aside **Omnilance** and wait a few seconds for a blood drop to form. The flow of blood will be helped keeping the hand warm, by lowering the hand to waist level, and by gentle massage of the finger.

For safety reasons, and to prevent crosscontamination, discard the used lancet into an appropriate sharps or biohazard container. Never allow another person to use a lancet that has already been used. If the lancing device is to be used by another person, the unit must be provided with a new tip and sterile lancet.

Omnican® lancet removal:
Unscrew the **Omnilance** tip. Push ahead the lancet ejector with thumb and simultaneously pull out the sliding barrel to dispose the lancet.



Taking care of your Omnilance:
Use mild soap and water to wipe the outside of the lancing device. For more complete cleaning, remove the tip, wash the tip in warm water and rinse well.

Cleanliness:
Wash your hands with warm soapy water. Rinse and dry hands thoroughly. You may also use an alcohol wipe to clean the puncture area. Make sure it is completely dry before you obtain the blood sample. Dirt or perspiration may affect the test result.

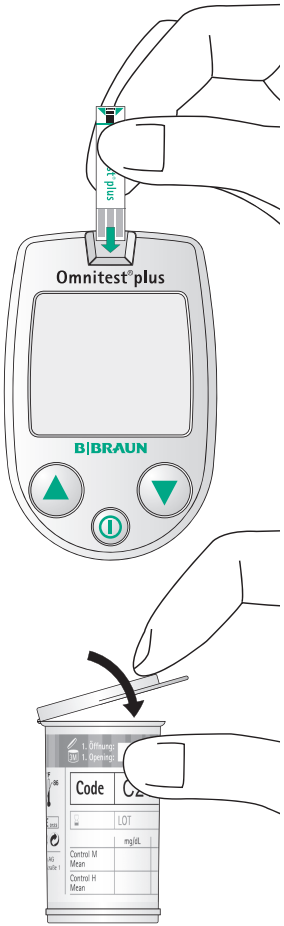
Lancing:
Prepare the lancing device and lancet. Insert a clean needle (lancet) in the lancing device. (Refer to page 32 for more information).

Note

Read the additional information given in the instructions for use of the test strips. Your healthcare professional will advice you on your ideal blood glucose range. Consult your physician before making any changes to your diabetes therapy.

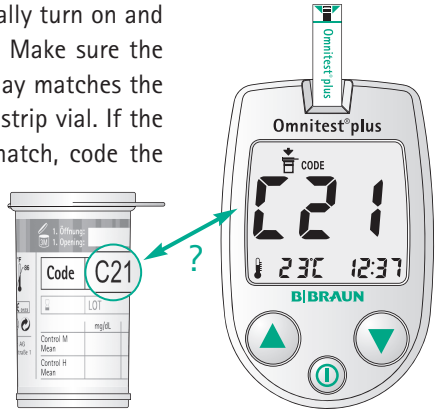
① Insert the Test Strip

Remove test strip from the vial. Recap the vial immediately to prevent moisture from affecting the other strips. Insert a test strip. Push the test strip until it will go no further without bending the strip.



② Compare the Code Number

The meter will automatically turn on and display the code number. Make sure the code number on the display matches the code number on the test strip vial. If the code number does not match, code the meter correctly.



Caution

If the code number on the display and on the test strip vial do not match, do the "Code the Meter" procedure, page 14 for accurate result. If any different message appears on the display due to several causes and conditions please refer to "Troubleshooting" page 46. Do not perform blood glucose tests at temperature below +10 °C (50 °F) or above +40 °C (104 °F) and above 90% relative humidity.

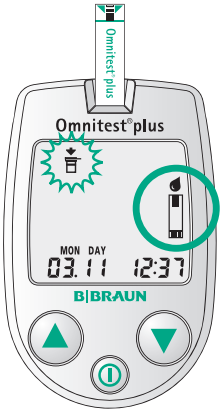
③ Applying Blood Sample

After 3 seconds of code confirmation blood icon will be displayed on the screen. Date and time information are shown at the bottom.

The blinking reminds you to close the test strip vial cap immediately.

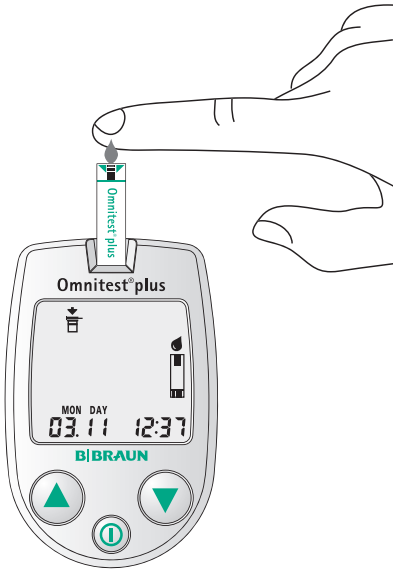
If you intend to change the code after 3 seconds have passed, pull the test strip out of the port, and re-start the procedure from the beginning.

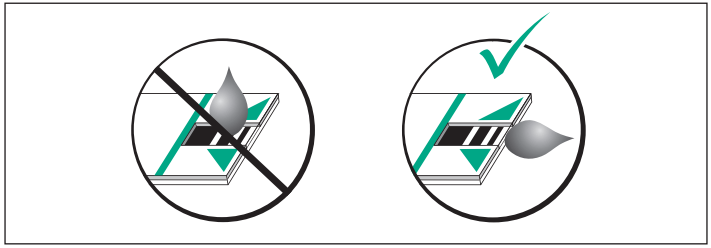
Prick the area where you have decided to obtain the blood.



④

Touch your finger to the tip of **Omnitest® plus** test strip.

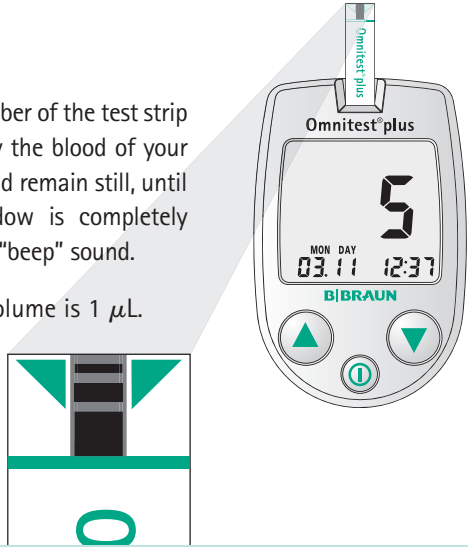




⑤

The measurement chamber of the test strip will draw automatically the blood of your finger. Your finger should remain still, until the confirmation window is completely filled and you hear the "beep" sound.

The minimal sample volume is 1 µL.



Note

Do not force your finger against the test strip. Do not try to apply a smeared sample. Do not add blood to the test strip after the "beep" sound. Do not squeeze the fingertip. The meter will power off automatically after 3 minutes, if no testing was done on the test strip. In this case, you have to re-insert the test strip.

Accurate Results in Seconds

After "beep" sounds, the test will begin automatically, counting down the numbers from 5 to 1 on the display.

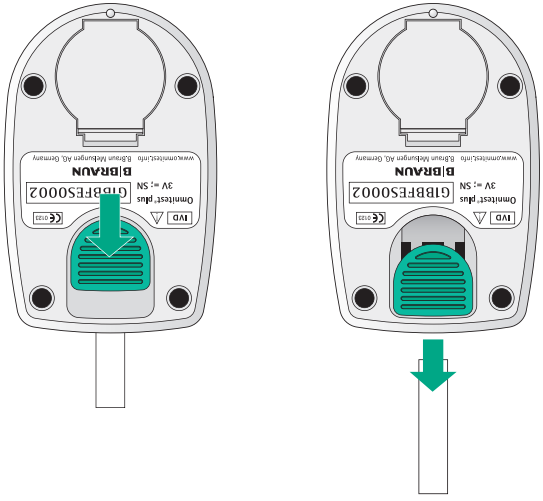
Then the test result will be shown.

Temperature information and date information are alternatively displayed under the test result.

Blood glucose test results are displayed on the **Omnitest® plus** meter as either milligrams of glucose per deciliter of blood (mg/dL) or millimoles of glucose per liter of blood (mmol/L), depending upon the test result unit selected (see page 27). The **Omnitest® plus** meter displays results between 10 ~ 600 mg/dL (0.6 ~ 33.3 mmol/L).

6 Remove Tested Strip by Ejector

Slide the ejector button forward to remove the test strip from the meter. The meter is turned off with the removal of the test strip. Discard the used strip and lancet to a proper place. Clean the meter if necessary according to "Maintain Your Blood Glucose Monitor System", page 44.



Maintain Your Blood Glucose Monitor Sys tem

Fore safe, accurate, and long-term use of the meter, be sure that the meter is maintained with proper care.

1.
The meter should be cared after test, and cleaned if necessary with soft cloth or paper tissues. Objects which had been in contact with blood bear the potential risk for transmitting an infectious disease. If necessary, alcohol swab can be used to wipe out dirt on the outer surface of the meter, but chemical solution such as benzene or acetone MUST NOT be used since either of those can harm and damage the meter surface. When cleansing the meter with pure alcohol, DO NOT pour directly onto the meter, but use the cloth soaked with properly small amount of alcohol. After cleansing the meter, dry completely at a cool place avoiding direct sunlight.

2.
Do not soak the meter and test strip into water or liquid. Use as properly as you can. Strong electromagnetic fields (e.g. mobile phones, microwave ovens) could disturb the meter function. Do not put the meter and strip near fire or microwave ovens.

3.
After test, put the parts of **Omnitest® plus** in the pouch together, and keep it at a cool and dry place out of the reach of children. Do not refrigerate. Avoid exposure to the sun.

4.
For detailed storage instructions for **Omnitest® plus** test strips, refer to the user's manual of **Omnitest® plus** test strip.

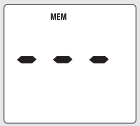
5.
The lancing device should be cleaned if blood or stain remains after test for infectious disease prevention.

6.
When you use up the lancets or lancing device is damaged, you can purchase them at your nearest pharmacy or B. Braun representative.

7.
Discharge used materials according to the local regulations for contaminated materials.

Troubleshooting

message	caused by	what to do?
	There is a problem with the meter. There is an abnormal Check Strip signal.	Repeat the Check Strip test 2 or 3 times. Do not use the meter. Contact B. Braun representative.
	Error message could be caused by a used or wet test strip.	Repeat the test with a new test strip.
	Poor amount of blood sample.	Retest with new test strip and sufficient blood sample.
	There is a problem with the test strip Test strip is damaged.	Repeat the test with a new test strip.
	Error message that indicates that the blood or control solution sample was applied before the symbol appeared on the display.	Repeat the test with new test strip. Apply blood or control solution only after the symbol appears on the display.

message	caused by	what to do?
	No results obtained on the meter.	The meter memory is empty until you perform a first blood glucose measurement.
	The test result is higher than 600 mg/dL (33.3 mmol/L).	In case of doubt of blood test result, check the meter with control solution. With normal result, re-test with blood sample two or three times. When "HI" message persists, please consult a doctor for assistance.
	The test result is lower than 10 mg/dL (0.6 mmol/L).	In case of doubt of blood test result, check the meter with control solution. With normal result, re-test with blood sample two or three times. When "Lo" message persists, please consult a doctor for assistance.

Troubleshooting

message	caused by	what to do?
	The ambient temperature is too low.	Place the meter at the operating temperature range 10 ~ 40 °C (50 ~ 104 °F) for more than 10 minutes and re-test.
	The ambient temperature is too high.	Place the meter at the operating temperature range 10 ~ 40 °C (50 ~ 104 °F) for more than 10 minutes and re-test.

problem	caused by	what to do?
Different result in comparison with an other meter.	Meter is calibrated against whole blood from the manufacturer.	To check the accuracy of your system use **Omnitest® plus Control** control solution or measure against a laboratory device which uses plasma.
	Blood samples are not taken at the same time.	Repeat the measurement and take the samples at the same time for camparison.

problem	caused by	what to do?
The meter does not power on.	Battery is flat or there is a problem with the meter.	Change the battery and if the problem persists, contact your distributor or nearest B. Braun representative.
Test does not start after applying sample.	Poor amount of sample or there is a problem with test strip or meter.	Apply sufficient amount of sample to a new blood glucose test strip and re-test. Make sure you hear a beep sound before removing your finger from the test strip during testing. Conduct a control solution test or a check strip test.
The result is doubtful.	There may be a problem with the test strip.	Re-test with a new test strip. Conduct a control solution test.
	The codes of the meter and of the test strip vial do not match.	Re-code the meter and re-test.

Specifications

Test Range	10 ~ 600 mg/dL 0.6 ~ 33.3 mmol/L
Reading Time	5 sec.
Memory Capacity	250 test results
Operating Temperature	10 °C ~ 40 °C 50 °F ~ 104 °F
Operating Humidity	10 ~ 90 %
Sample Type	Fresh capillary whole blood
Sample Volume	1.0 µL
Display Type	LCD
Size (L x W x H)	79 x 51 x 18 mm
Weight including battery	41 g
Power Supply	1 x 3V Li battery (CR2032)
Battery Life	Running 3000 tests

Symbol	Description
	Consult operating instructions
	Used By
CE 0123	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices
	Caution, consult accompanying documents
IVD	In-Vitro-Diagnosticum
LOT	Batch code
REF	Catalogue number
	Store at
	Do not re-use
	Use within 3 months after first opening

Specifications

Test Principle:
The enzyme glucose oxidase on the test strip reacts specifically with the blood glucose. The current generated is converted and displayed as blood glucose value.

The **Omnitest® plus** system is plasma-calibrated to allow easy comparison of results with laboratory methods.

Blood glucose meter which are calibrated against a whole blood method may have different results in comparison to **Omnitest® plus**. The laboratory system used for calibration of the **Omnitest® plus** system is YSI 2300 STAT plus which is equipped with a glucose oxidase system.

Transfer Test Results to a Computer

You can transfer test results from the **Omnitest® plus** meter to a computer, where the data can be further analyzed. To make use of this feature, you need the **Omnitest® plus** PC interface cable REF 9152806G and compatible software e.g. Diabass (ISBN 3-9806130-2-X).
The monitor will display PC as soon as the cable is connected to the PC and the software is activated.

For further information see
www.diabass.info or
www.omnitest.bbraun.com

Blood Glucose Conversion Table

Blood Glucose Conversion Table (mmol/L to mg/dL)

mmol/L	0.55	1.0	1.5	2.0	2.2	2.5	2.8	3.0	3.3	3.9	4.0	4.4	4.7	5.0	5.5	6.0	6.1
mg/dL	10	18	27	36	40	45	50	54	60	70	72	80	85	90	100	108	110

mmol/L	6.7	7.0	7.2	7.5	7.8	8.0	8.3	8.9	9.0	9.4	10.0	10.5	11.0	11.1	12.0	12.5	13.9
mg/dL	120	126	130	135	140	145	150	160	162	170	180	190	196	200	216	225	250

mmol/L	14.4	15.0	16.0	16.6	17.0	18.0	19.0	20.0	20.8	22.2	23.0	24.0	25.0	26.4	27.7	30.0	33.3
mg/dL	260	270	288	300	306	325	342	360	375	400	414	432	450	475	500	540	600

If you have any questions about the use of the **Omnitest® plus** system, please contact your nearest B. Braun representative or go www.omnitest.bbraun.com

B. Braun Melsungen AG
OPM
Carl-Braun-Straße 1
34212 Melsungen
Germany
Tel ++49 (0) 56 61 71-33 99
Fax ++49 (0) 56 61 71-35 50
www.bbraun.com
www.diabetes.bbraun.com

CE 0123 IVD

Date of last revision:
2009/05 B5MMGB

9154990GB

B BRAUN
SHARING EXPERTISE